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APPLICATION NO.	FI	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,702		01/12/2001	Todd Elliott Piper	P048411US0 PHI 1373	2735
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•		ES & SEASE, P.L	EXAMINER		
ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200				MEHTA, ASHWIN D	
DES MOIN	MOINES, IA 50309-2721				PAPER NUMBER
				1638	
				DATE MAILED: 08/29/2002 3	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
		09/759,702	PIPER, TODD ELLIOTT				
	Office Action Summary	Examiner	Art Unit				
·		Ashwin Mehta	1638				
	The MAILING DATE of this communication app		1				
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status 1)⊠	Responsive to communication(s) filed on 12 J	lanuary 2001	•				
1/⊠ 2a)[]	•	is action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 1-32 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-32</u> is/are rejected.							
7)	Claim(s) is/are objected to.						
8)□	Claim(s) are subject to restriction and/or	r election requirement.					
Applicati	on Papers						
9)⊠ The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) 🗌 -	The proposed drawing correction filed on		oved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.							
· —	The oath or declaration is objected to by the Ex	aminer.					
•	inder 35 U.S.C. §§ 119 and 120						
/	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents						
2. Certified copies of the priority documents have been received in Application No							
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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### **DETAILED ACTION**

### **Specification**

1. The specification is objected to for the inclusion of blank lines, on page 7 in the bottom paragraph.

# Claim Objections

2. Claims 1, 5, 7, 6, 12, 16, 25, and 29 are objected to.

In claims 1, 5, and 7: the claims are objected to for the inclusion of a blank line where the ATCC Accession number should appear.

In claims 6, 12, 16, 25, and 29: in line 1 of the claims, "A" should be -- The--.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "37Y15" in claims 1, 5, 7, 11, 15, 19, 24, 28, and 32 render the claims and those dependent thereon indefinite. Since the name "37Y15" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "37Y15" does not clearly identify the

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claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and the specific characteristics associated therewith could be modified. Amending claims 1, 5, and 7 to recite the ATCC deposit number in which hybrid maize seed 37Y15 has been deposited would overcome the rejection.

In claim 6: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 5.

In claims 8 and 21: it is not clear if the claim is directed towards detasseled plants, or plants that have been transformed with a gene conferring male sterility. Claims 8 and 21 also appear to broaden the scope of their parent claims. The parent claims are drawn to plants with a defined set of traits, and claims 8 and 21 add an additional trait. The following amendments are suggested: 1) in claims 8 and 21, replace "male sterile" with --detasseled--; 2) add a new claim 33 directed towards a method of producing a male sterile maize plant comprising transforming the maize plant of claim 2 with a nucleic acid that confers male sterility, and a new claim 34 directed towards a male-sterile maize plant produced by the method of claim 33.

In claims 11, 15, 19, 24, 28, and 32: the terms "excellent," "strong," "good," and "suited" are relative terms that have no definite meaning. The terms do not reasonably apprise one of the scope of the invention.

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In claims 10, 14, 18, 23, 27, and 31: the claims are indefinite for improper antecedent basis. The claims indicate that they are directed to the corn plant breeding program of claims 9, 13, 17, 22, 26, and 30, respectively. However, claims 9, 13, 17, 22, 26, and 30 are directed to methods, not programs. It is suggested that the recitation "corn plant breeding program" in line 1 of claims 10, 14, 18, 23, 27, and 31 be replaced with --method--.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8-19, and 21-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards a corn plant produced by growing seed of any hybrid maize seed designated 37Y15, wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 37Y15 and expresses a combination of at least two 37Y15 traits; or a hybrid maize plant grown from seed of 37Y15, or which has all the morphological and physiological traits as the plant grown from 37Y15 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and

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which expresses at least 2 37Y15 traits; or a hybrid maize plant grown from 37Y15 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least 2 37Y15 traits.

The specification describes morphological and physiological traits of a hybrid maize plant grown from hybrid maize seed arbitrarily designated "37Y15", which was produced by crossing two inbred lines designated "GE571367" and "GE533418" (page 7, last paragraph; page 17; Table 1, pages 18-20). The specification also describes comparisons of 37Y15 to other hybrid plants (pages 21, Tables 2A-2C on pages 22-27, page 28, Table 3 on page 29, page 30, first paragraph and Table 4). The specification further indicates that upon allowance of any claims, all restrictions on the availability to a deposit of 2500 seeds of 37Y15 with the American Type Culture Collection will be removed, that the deposit will be maintained without restriction, that all requirements of 37 CFR 1.801-1.809 will be met, and that the deposit will follow the requirements of 37 CFR 1.801-1.809 (page 45).

However, the specification does not describe 37Y15 as being male sterile. The specification discusses how plants may be manipulated to become male sterile (paragraph bridging pages 2 and 3 and the first full paragraph of page 3). However, the morphological and physiological description of plant 37Y15 in the specification does not indicate that it is male sterile.

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The specification also does not describe the plants developed by the maize breeding programs, transgenic 37Y15 plants, 37Y15 plants further comprising genes transferred by backcrossing, or maize plants wherein at least one ancestor is corn variety 37Y15 and which express at least two of the traits listed in claims 11, 15, 19, 24, 28, or 32. The morphological and physiological traits of the corn plants that are crossed with 37Y15, and with progeny of that cross, are unknown, and the description of progeny and descendents of corn plant 37Y15 are unknown. The description of corn plant 37Y15 is not indicative of any of its descendents. To say that a plant expresses two traits of another plant is not sufficient information to describe that plant, as numerous corn plants express at least two of the same traits as those expressed by 37Y15. Two plant traits do not provide any description of the other traits of a plant. It is possible that the claimed plants inherited the genes governing those traits from an ancestor other than plant 37Y15. For example, Kevern (U. S. Patent No. 6,242,673) describes a corn plant designated "37M34," which has at least two traits in common with 37Y15, exceptional yield potential and a relative maturity of approximately 99 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, for example (col. 12, lines 8-19). The instantly claimed corn plants could have 37M34 as an ancestor, as well as 37Y15, in which case the yield potential and relative maturity traits, for example, could have been inherited from 37M34. Further, it is not known what genes of 37Y15 would be affected in the claimed methods comprising breeding programs. The traits of the plants produced by the programs are unknown, and are not described by the specification. The transgenes, and genes introduced into 37Y15 by backcrossing, may be of gene(s) that effect any trait or more than one trait. Such plants would express different morphological and physiological traits from 37Y15, and which are not

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described. For claims 12 and 25, it is suggested that the claims be amended to list the types of transgenes contemplated in the specification, for example disease or pest resistance genes, provided the prior art teaches those isolated genes. Given the breadth of the claims encompassing corn plant 37Y15 having male sterility, corn plants expressing at least two traits that are also expressed by 37Y15, any transgenic 37Y15 plant, any 37Y15 plant further having any gene(s) introduced by backcrossing, methods comprising the use of such plants, lack of guidance of the specification as discussed above, the specification fails to provide an adequate written description of the multitude of corn plants and their parts encompassed by the claims.

5. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards hybrid maize seed designated "37Y15"; a corn plant produced by growing seed of any hybrid maize seed designated 37Y15, or parts thereof; or wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 37Y15 and expresses a combination of at least two 37Y15 traits; or a hybrid maize plant grown from seed of 37Y15, or which has all the morphological and physiological traits as the plant grown from 37Y15 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and which expresses at least 2 37Y15 traits; or a hybrid

maize plant grown from 37Y15 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing and which expresses at least 2 37Y15 traits.

Since the claimed seed of maize hybrid line 37Y15 is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. Applicant's intent to deposit the seed with the ATCC is acknowledged (page 45).

If the seeds are deposited under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must by maintained.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of

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compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

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(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
  - (e) the deposit will be replaced if it should ever become inviable.

## Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kevern (U.S. Patent No. 6,242,673).

The claims are broadly drawn towards hybrid maize seed designated "37Y15"; a corn plant produced by growing seed of any hybrid maize seed designated 37Y15, or parts thereof; or wherein said plant is male sterile; or any maize plant or its parts wherein at least one ancestor is 37Y15 and expresses a combination of at least two 37Y15 traits; or a hybrid maize plant grown from seed of 37Y15, or which has all the morphological and physiological traits as the plant grown from 37Y15 seed, and which contains one or more transgenes; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more transgenes; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more transgenes and which expresses at least 2 37Y15 traits; or a hybrid maize plant grown from 37Y15 seed wherein the genetic material contains one or more genes transferred by backcrossing; or a method for developing a maize plant in a maize plant breeding program comprising said hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing; or any maize plant wherein at least one ancestor is the hybrid maize plant comprising one or more genes transferred by backcrossing one or more genes transferred by backcrossing one or more genes transferred by backcrossing and which expresses at least 2 37Y15 traits.

Kevern teaches seed of a hybrid maize line designated "37M34," plants produced by growing said seed, and plants and plant parts, including pollen and ovules (col. 12, lines 7-19,

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Table 1; col. 15, line 29 to col. 21, line 17, Tables 2A-2B; Tables 3 and 4; col. 25, lines 3-7 and col. 26, lines 1-7; claims). It appears that the claimed plants and seeds of the instant invention may be the same as 37M34, given that they exhibit similar traits, such as exceptional yield potential and a relative maturity of approximately 99 based on the Comparative Relative Maturity Rating System for harvest moisture of grain, for example (col. 12, lines 9-12, Table 1). Alternatively, if the claimed plants, plant parts, and seeds of 37Y15 are not identical to 37M34, then it appears that 37M34 only differs from the instantly claimed plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 37Y15. Kevern also teaches methods to confer male sterility to corn plants, and assert that large-scale commercial maize hybrid production require the use of some form of male sterility, and that a reliable method of controlling male fertility in plants also offers the opportunity for improved plant breeding (col. 1, line 53 to col. 2, line 60). It would have been obvious and within the scope of one of ordinary skill in the art to make plant 37M34 male sterile, following one of the methods taught by Kevern. One would have been motivated to make 37M34 male sterile, given its requirement for hybrid production and importance for improved plant breeding, as taught by Kevern. Kevern also teaches production of tissue culture of regenerable cells from a plant of line 37M34, wherein regenerable cells are from tissues including flowers, pollen, ovules, among others; a plant produced from tissue culture of 37M34 that is capable of expressing all of the morphological and physiological traits of 37M34; corn plant breeding programs, including backcrossing, pedigree breeding, recurrent selection, among others; maize lines derived from 37M34, or from 33626

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containing one or more transgenes, or from 37M34 containing one or more genes transferred by backcrossing; use of backcrossing to introduce gene(s) for desirable traits; 37M34 comprising at least one transgene, and using the plant in maize breeding programs; maize plants produced by those breeding programs, 37M34 comprising genes(s) introduced by backcrossing, and use of the plant in a method for developing a plant for breeding programs (col. 2, line 61 to col. 5, line 59; col. 21, line 18 to col. 30, line 28; claims). The claimed invention was *prima facie* obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by Kevern.

### 7. No claim is allowed.

# **Contact Information**

Any inquiry concerning this communication from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 23, 2002

ASHWIN D. MEHTA, PH.D.
PATENT EXAMINER